

## Subpart B—Exemptions

### § 174.21 General qualifications for exemptions.

A plant-incorporated protectant is exempt from the requirements of FIFRA, other than the requirements of § 174.71, if it meets all of the following criteria:

(a) The plant-incorporated protectant meets the criteria listed in at least one of the sections in §§ 174.25 through 174.50.

(b) When the plant-incorporated protectant is intended to be produced and used in a crop used as food, the residues of the plant-incorporated protectant are either exempted from the requirement of a tolerance under FFDCA (as amended, 21 U.S.C. 321 *et seq.*) as codified at §§ 174.507 through 174.508, or no tolerance would otherwise be required for the plant-incorporated protectant.

(c) Any inert ingredient that is part of the plant-incorporated protectant is on the list codified at § 174.705. Plant-incorporated protectants that are not exempt from the requirements of FIFRA under this subpart are subject to all the requirements of FIFRA.

[66 FR 37814, July 19, 2001, as amended at 72 FR 20434, Apr. 25, 2007]

### § 174.25 Plant-incorporated protectant from sexually compatible plant.

A plant-incorporated protectant is exempt if all of the following conditions are met:

(a) The genetic material that encodes the pesticidal substance or leads to the production of the pesticidal substance is from a plant that is sexually compatible with the recipient plant.

(b) The genetic material has never been derived from a source that is not sexually compatible with the recipient plant.

## Subpart C—Registration Procedures and Requirements [Reserved]

## Subpart D—Monitoring and Recordkeeping

### § 174.71 Submission of information regarding adverse effects.

(a) Any person who produces, for sale or distribution, a plant-incorporated protectant exempt under subpart B of this part, who obtains any information regarding adverse effects on human health or the environment alleged to have been caused by the plant-incorporated protectant must submit such information to EPA. This requirement does not apply to any person who does not produce a plant-incorporated protectant exempt under subpart B of this part. This may include, for example, researchers performing field experiments, breeders making crosses among plant varieties with the goal of developing new plant varieties, or a person who only sells propagative materials (e.g., seed) to farmers without producing the propagative materials themselves. EPA must receive the report within 30 calendar days of the date the producer first possesses or knows of the information.

(b) Adverse effects on human health or the environment for purposes of plant-incorporated protectant means at a minimum information about incidents affecting humans or other nontarget organisms where both:

(1) The producer is aware, or has been informed, that a person or nontarget organism allegedly suffered a toxic or adverse effect due to exposure to (e.g., ingestion of) a plant-incorporated protectant.

(2) The producer has or could reasonably obtain information concerning where the incident occurred.

(c) All of the following information, if available, must be included in a report.

(1) Name of reporter, address, and telephone number.

(2) Name, address, and telephone of contact person (if different than reporter).

(3) Description of incident.

(4) Date producer became aware of incident.

(5) Date of incident.

(6) Location of incident.

(d) Reports and questions should be submitted to the Office of Pesticide

## Environmental Protection Agency

## § 174.505

Programs' Document Processing Desk at the appropriate address as set forth in 40 CFR 150.17(a) or (b).

[66 FR 37814, July 19, 2001, as amended at 71 FR 35546, June 21, 2006]

### Subparts E–F [Reserved]

### Subpart G—Labeling [Reserved]

### Subpart H—Data Requirements [Reserved]

### Subpart I [Reserved]

### Subpart J—Good Laboratory Practices [Reserved]

### Subpart K—Export Requirements [Reserved]

### Subparts L–T [Reserved]

### Subpart U—Experimental Use Permits [Reserved]

### Subpart V [Reserved]

### Subpart W—Tolerances and Tolerance Exemptions

#### § 174.500 Scope and purpose.

This subpart lists the tolerances and exemptions from the requirement of a tolerance for residues of plant-incorporated protectants in or on food commodities.

[72 FR 20434, Apr. 25, 2007]

#### § 174.501 *Bacillus thuringiensis* Vip3Aa protein in corn and cotton; exemption from the requirement of a tolerance.

Residues of *Bacillus thuringiensis* Vip3Aa proteins in or on corn or cotton are exempt from the requirement of a tolerance when used as plant-incorporated protectants in or on the food and feed commodities of corn; corn, field; corn, sweet; corn, pop; and cotton; cotton, undelinted seed; cotton, refined oil; cotton, meal; cotton, hay; cotton, hulls; cotton, forage; and cotton, gin byproducts.

[73 FR 45624, Aug. 6, 2008]

#### § 174.502 *Bacillus thuringiensis* Cry1A.105 protein; exemption from the requirement of a tolerance.

(a) Residues of *Bacillus thuringiensis* Cry1A.105 protein in or on the food and feed commodities of corn; corn, field, flour; corn, field, forage; corn, field, grain; corn, field, grits; corn, field, meal; corn, field, refined oil; corn, field, stover; corn, sweet, forage; corn, sweet, kernel plus cob with husk removed; corn, sweet, stover; and corn, pop, grain and corn, pop, stover are exempt from the requirement of a tolerance when the *Bacillus thuringiensis* Cry1A.105 protein is used as a plant-incorporated protectant in these food and feed corn commodities.

(b) A time-limited exemption from the requirement of a tolerance is established for residues of *Bacillus thuringiensis* Cry1A.105 protein in or on the food and feed commodities of cotton; cotton, forage; cotton, gin byproducts; cotton, hay; cotton, hulls; cotton, meal; cotton, refined oil; and cotton, undelinted seed when the *Bacillus thuringiensis* Cry1A.105 protein is used as a plant-incorporated protectant in these food and feed cotton commodities. The exemption from the requirement of a tolerance expires and is revoked on November 22, 2010.

[74 FR 39543, Aug. 7, 2009]

#### § 174.504 *Bacillus thuringiensis* Cry1F protein in cotton; exemption from the requirement of a tolerance.

Residues of *Bacillus thuringiensis* Cry1F protein in cotton are exempt from the requirement of a tolerance when used as a plant-incorporated protectant in food and feed commodities of cotton.

[72 FR 20434, Apr. 25, 2007]

#### § 174.505 *Bacillus thuringiensis* modified Cry3A protein (mCry3A) in corn; exemption from the requirement of a tolerance.

Residues of *Bacillus thuringiensis* modified Cry3A protein (mCry3A) in corn are exempt from the requirement of a tolerance when used as plant-incorporated protectant in the food and feed commodities of corn; corn, field; corn, sweet; and corn, pop.

[72 FR 20434, Apr. 25, 2007]